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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,297	03/31/2006	Cindy Castado	VB60452	9309

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
11/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/574,297	CASTADO ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/26/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,23-36,53-69,71 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13,23-36,53-69,71 and 72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

The restriction on 6/24/2008 has been vacated.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I: claims 1-5, drawn to an immunogenic composition comprising a polypeptide and a pharmaceutically acceptable excipient.
2. Group II: claims 6-8 drawn to an immunogenic composition comprising a polynucleotide.
3. Group III: claims 9-10 drawn to an immunogenic composition comprising a polynucleotide encoding a polypeptide.
4. Group IV: claims 11-13, 23-36, 53-66, and 72 drawn to an immunogenic composition comprising at least or exactly two, three, four, five six, seven, eight, nine or ten different Bordetella antigens.
5. Group V: claims 69-70 drawn to a method for treating or preventing Bordetella infection.

6. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I, an immunogenic composition comprising a polypeptide comprising an amino acid sequence which has at least 85% identity to SEQ ID NO: 34, over the entire length of SEQ ID NO: 34, or an immunogenic fragment

thereof, and a pharmaceutically acceptable excipient. The technical feature is unpatentable over Wang et al WO200277183-A2 Date October 3, 2002. Wang et al teach a polypeptide comprising an amino acid sequence which has at least 85% identity to SEQ ID NO: 34 (see Claim 25; SEQ ID NO 50795).

7. The technical feature of Group II is immunogenic composition comprising a polynucleotide.
8. The technical feature of Group III is an immunogenic composition comprising a polynucleotide encoding a polypeptide.
9. The technical feature of Group IV is an immunogenic composition comprising at least or exactly two, three, four, five six, seven, eight, nine or ten different Bordetella.
10. Group V: claims 69-70 drawn to a method for treating or preventing Bordetella infection.

Group I lacks unity with Groups II-V, because the technical feature of Group I is anticipated by the art and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.

Election of Species Requirement to Group IV

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Bordetella adhesin and toxin/invasion Antigen Election of Species

Groups IV read on patentably distinct composition comprising proteins and antigens. Each protein/antigen is patentably distinct because they have different biochemical and immunological properties and a further restriction is applied to each Group.

Applicant is advised that examination will be restricted only to the elected species election for Group IV for the combinations included in an immunogenic composition that may comprise species from Group A, Group B4 and B5, Group C, or Group D below.

Polypeptide Election Requirement to Group IV

In addition, Group IV read on patentably distinct sequences. Each sequence is patentably distinct because they are structurally different and a further restriction is applied to each Group.

Applicant is advised that examination will be restricted to only the elected nucleotide sequence(s) and should not be construed as a species election for the immunogenic composition from SEQ ID NOs: from B1-B3. Thus examination should not be construed as a species election for polypeptide election but considered as one nucleotide sequence per Group.

Election for Group IV as follows:

Applicant is required to elect a specific single individual species from Group A, and to further elect a specific combination from Group B (election of SEQ ID NO(s) and species 4-5), from Group C (species 1-4), and from Group D (species 1-4) for the immunogenic composition.

For Example: Immunogenic Composition comprises elected species A2 comprising 3 antigens which includes SEQ ID NO: 34, an antigenic fragment thereof of SEQ ID NOs: 2, and febrile 3.

Group A Bordetella antigens species:

A. Applicant must elect a specific number of at least 2 or more antigens but no more than ten different antigens in the immunogenic compositions:

Bordetella antigens:

1) two antigens

2) three antigens

3) four antigens

4) five antigens

5) six antigens

6) seven antigens

7) eight antigens

8) nine antigens

9) ten antigens

Group B: Election of Species and Election of SEQ ID NO(s):

B. Applicant must further elect a combination from 1-5 of polypeptides with of SEQ ID Nos: from Groups 1-3 and/or proteins from Groups 3-5 which equals the same number of the specific number of antigens that was previously selected in Group A as follows.

1) Bordetella autotransporter protein selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID NO: 34.

2) Bordetella iron acquisition protein selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID NOs: from the list below:
a) SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, or 28;
or

b) an antigenic fragment thereof of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, or 28;

3) Bordetella iron acquisition protein selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID NOs: from the list below:
a) SEQ ID NOs: 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, or 98;
or
b) an antigenic fragment thereof of SEQ ID NOs: 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, or 98;

4) Bordetella adhesin/Bordetella adhesin antigenic fragment thereof

a) FHA

b) febrile 2 and/or febrile

d) pertactin

e) BrkA

f) antigenic fragment of FHA

g) antigenic fragment of febrile 2 and/or 3

h) antigenic fragment of pertactin

i) antigenic fragment of BrkA

5) Bordetella toxin/invasion or antigens or antigenic fragment thereof involved in toxin/invasin secretion

a) pertussis toxin

b) adenylate cyclase

c) dermonecrotic toxin (Dnt)

d) Type III ss

e) lipopolysaccharide

f) antigen fragment pertussis toxin

g) antigen fragment adenylate cyclase

h) antigen fragment dermonecrotic toxin (Dnt)

i) antigen fragment Type III ss

j) antigen fragment lipopolysaccharide

Note: Bordetella antigens in the immunogenic composition do not consist of any combination of 2, 3, 4, or all 5 of pertactin, febrile 2, febrile 3, FHA and pertussis toxin as stated in claim for the combination.

Furthermore,

If Applicant's elect a combination comprising Bordetella iron acquisition protein from B2: (claim 12)

Applicant must further elect:

2) Bordetella iron acquisition protein selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID NOs: from the list below:

a) SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, or 28;

or

b) an antigenic fragment thereof of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, or 28;

Furthermore,

If Applicant's elect a combination comprising Bordetella iron acquisition protein from B3: (claim 23)

Applicant must further elect:

Bordetella iron acquisition protein selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID NOs: from the list below:
a) SEQ ID NOs: 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, or 98;
or
b) an antigenic fragment thereof of SEQ ID NOs: 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, or 98;

Furthermore,

If Applicant's elect a combination comprising Bordetella adhesin/Bordetella adhesion from B4: (claim 29)

Applicant must further elect:

4) Bordetella adhesin/Bordetella adhesin antigenic fragment thereof

a) FHA

b) febrile 2 and/or febrile

d) pertactin

e) BrkA

f) antigenic fragment of FHA

g) antigenic fragment of febrile 2 and/or 3

h) antigenic fragment of pertactin

i) antigenic fragment of BrkA

Furthermore,

If Applicant's elect a combination comprising Bordetella toxin/invasion or antigens from B5: (claim 32)

Applicant must further elect:

5) Bordetella toxin/invasion or antigens or antigenic fragment thereof involved in toxin/invasin secretion

a) pertussis toxin

b) adenylate cyclase

c) dermonecrotic toxin (Dnt)

d) Type III ss

e) lipopolysaccharide

f) antigen fragment pertussis toxin

g) antigen fragment adenylate cyclase

h) antigen fragment dermonecrotic toxin (Dnt)

i) antigen fragment Type III ss

j) antigen fragment lipopolysaccharide

Note: Bordetella antigens in the immunogenic composition do not consist of any combination of 2, 3, 4, or all 5 of pertactin, febrile 2, febrile 3, FHA and pertussis toxin as stated in claim for the combination.

Election of Species

As set forth supra, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Phase Election Requirement to Group IV

In addition, Group IV election of species detailed above read on patentably distinct time periods. Each phase is patentably distinct because each can affect different biochemical and immunological properties to a polypeptide and a further restriction is applied.

Group C:

Phase species

1) Bvg+ early phase;

2) Bvg+ late phase;

3) Bvgi phase;

4) Bvg- phase;

Antigen Election Requirement to Group IV

In addition, Group IV election of species, detailed above, read on patentably distinct composition comprising antigens. Each antigen is patentably distinct because they have different biochemical and immunological properties and a further restriction is applied.

Group D:

Species of Antigens

1) Toxoid

2) PRP capsular oligosaccharide or polysaccharide from Haemophilus Influenzae B Polysaccharide;

3) Hepatitis B surface antigen (HbsAg);

4) Inactivated Polio Vaccine (IPV);

5) N. meningitidis protein;

6) Men A, C, W, or Y capsular polysaccharides or oligosaccharides;

7) Capsular polysaccharides or oligosaccharides from S. pneumoniae;

8) Killed Attenuated Hepatitis A virus.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Archie whose telephone number is 571-272-9938. The examiner can normally be reached on M-F 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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